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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/823,980 03/25/97 WEINER A CHIR-0108

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HM22/0531

EXAMINER

SCHWADRON, R	
ART UNIT	PAPER NUMBER

1644 27
DATE MAILED: 05/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/823,980

Applicant(s)
Weiner et al.

Examiner
Ron Schwadron, Ph.D.

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1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/23/2000 and 7/17/2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-54 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

1. The amendment filed 6/23/2000 has necessitated the following supplemental Office Action. The period of response will begin as of the mailing date of this Office Action.
2. Claims 40-54 are under consideration.
3. References not considered in the IDS filed 7/17/2000 were already of record on a previously mailed PTO 892 or a copy of said reference was not supplied (references marked with an asterisk).
4. The objection to the amendment filed 2/1/99 under 35 U.S.C. 132 as enunciated in paragraph 3 of the Office Action mailed 7/3/2000 is withdrawn in view of the Weiner declaration filed 6/23/2000.
5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. The rejection of claims 40-42,45,48,49,52,53 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as enunciated in paragraph 5 of the Office Action mailed 7/3/2000 is withdrawn in view of the Weiner declaration filed 6/23/2000.
7. Claims 40-42,45,48,49,52-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.
 - A) There is no support in the specification as originally filed for the recitation of

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“wherein the immunogenic peptide does not contain any other sequence corresponding to a hypervariable domain of hepatitis C virus” in the context recited in claim 40. There is no written description in the specification as originally filed of the claimed invention (eg. it constitutes new matter).

Regarding applicants comments, while the specification defines the E2 hypervariable region as amino acids 384-414, there is no disclosure in the specification of the claimed invention which is a polypeptide comprising the amino sequence recited in the claims “wherein the immunogenic peptide does not contain any other sequence corresponding to a hypervariable domain of hepatitis C virus”. Applicant has not pointed out support for the claimed invention in the specification or claims as originally filed. In fact, applicant has indicated that said limitation is not disclosed in the specification (see page 11, last paragraph of amendment filed 6/23/2000). Regarding applicants comments that said limitation is an inherent property of the disclosed peptide, there is no disclosure in the specification as originally filed of the claimed peptide with said limitation.

B) There is no support in the specification as originally filed for the immunogenic composition of claim 52. The specification discloses a “vaccine” with the components recited in claim 52 (pharmaceutically acceptable carrier and peptide), but not an immunogenic composition with said ingredients. The terms “immunogenic composition” and “vaccine” are not interchangeable (eg. vaccine reads on composition for treating human disease , wherein immunogenic composition has a variety of in vitro uses).

8. Claims 50 and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50 and 51 lack antecedent basis in claim 40, wherein claim 40 recites “wherein the immunogenic peptide does not contain any other sequence corresponding to a hypervariable domain of hepatitis C virus”

9. No claim is allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile

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transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RON B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800 (wv)

Ron Schwadron, Ph.D.
Primary Examiner
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